IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

GCE GAS CONTROL EQUIPMENT INC.,
909 Rose Ave., 8th Floor
North Bethesda, MD 20852
(Montgomery County),

Plaintiff,

v.

3B MEDICAL MANUFACTURING, LLC, 203 Ave. A N.W. Winter Haven, FL 33881,

Defendant.

C.A. No. 22-	C.A.	No.	22-				
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DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff GCE Gas Control Equipment Inc. ("Plaintiff" or "GCE"), by its attorneys, brings this action against Defendant 3B Medical Manufacturing, LLC ("Defendant" or "3B"). GCE seeks a declaration of non-infringement under the Declaratory Judgment Act regarding U.S. Patent Nos. 10,357,628 (the "628 Patent") and 11,389,614 (the "614 Patent") (collectively, the "Patents-in-Suit").

Nature of the Action

1. This is an action arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and the patent laws of the United States, Title 35 of the United States Code, seeking declaratory judgment of non-infringement of the Patents-in-Suit.

Parties

 Plaintiff GCE is a corporation organized and existing under the laws of Delaware with its principal place of business located at 909 Rose Ave., 8th Floor, North Bethesda, Maryland 20852.

- 3. On information and belief, Defendant 3B Medical Manufacturing, LLC is a limited liability company organized and existing under the laws of Florida and has its principal place of business at 203 Ave. A N.W., Winter Haven, Florida 33881. The Florida registered agent for 3B Medical Manufacturing, LLC is "CFO," Daniel Newberry, 203 Ave. A N.W., Winter Haven, Florida 33881.
- 4. On information and belief, 3B Medical Manufacturing, LLC is doing business as React Health.

Jurisdiction and Venue

- 5. This Court has subject matter jurisdiction over GCE's claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 because this action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*
- 6. This Court has personal jurisdiction over 3B because it purposely availed itself of this forum by sending demand letters to and corresponding with GCE—who, at all relevant times, was located in this District. 3B's demand letters and correspondence threaten legal action against GCE. Specifically, on at least the dates of July 24, 2020, September 25, 2020, and then nearly two years later on July 28, 2022, 3B, through its counsel, sent letters via electronic mail to GCE—headquartered in this District—alleging infringement of the Patents-in-Suit based on GCE's Zen-O lite system.
- 7. GCE resides in Maryland, maintains headquarters in Maryland, and regularly conducts business in Maryland. For example, GCE markets, sells and services the Zen-O lite system in and from this District. Further, GCE provides and/or directs its products and services at customers living in counties served by this District.

- 8. Venue is proper in this District under 28 U.S.C. §§ 1391(b)-(c) because Defendant is subject to personal jurisdiction in this District.
- 9. An actual and justiciable controversy exists between GCE and Defendant and is currently ripe for adjudication. As set forth above, Defendant has sent multiple cease and desist letters to GCE asserting that GCE's manufacturing and sale of the Zen-O lite system infringes the '628 and '614 Patents, demanding that GCE cease further sales of the Zen-O lite system, and threatening legal action. Defendant has demanded that GCE immediately cease and desist from manufacturing, using, offering to sell, selling, and importing the Zen-O lite system.
- 10. GCE's products, including the Zen-O lite system, do not infringe the Patents-in-Suit.
- 11. Defendant's demands and the underlying assertions of infringement of the Patents-in-Suit threaten injury to GCE, have created an actual and substantial controversy, and have placed a cloud over GCE's rights to continue producing and selling its Zen-O lite system.

Background

- 12. GCE is a leader in technically advanced pressure equipment and flow control of high pressure gases. In particular, GCE designs, makes, and sells a variety of medical devices and parts (*see*, *e.g.*, https://us.gcegroup.com/sectors/medical#).
- 13. Defendant alleges that GCE's Zen-O lite system infringes the Patents-in-Suit. The Zen-O lite system is a medical device, in particular, a portable oxygen concentrator system that breathes new life to patients in need of oxygen therapy. While non-portable oxygen concentrators can provide oxygen therapy, portable oxygen concentrators are necessary for certain patients who are in constant need of oxygen therapy. Without the portability, such

patients would be immobile—this system allows patients to freely move and visit different places while still receiving the oxygen therapy they need.

- 14. On July 24, 2020, Defendant sent a letter to GCE representing that 3B Medical Manufacturing, LLC is the exclusive licensee of the '628 Patent and asserting that GCE infringes the '628 Patent by manufacturing and selling the Zen-O lite system in the United States. The letter stated that "GCE's Zen-O lite system infringes one or more claims of [the '628 Patent.]"
- 15. In the July 24, 2020 letter, Defendant stated that 3B is "committed to aggressively protecting its intellectual property rights."
- 16. GCE responded that GCE has not infringed, and does not infringe, any claim of the '628 Patent.
- 17. Subsequent to its initial correspondence, Defendant sent a letter to GCE asserting that GCE infringes the '628 Patent. The letter stated that GCE "infringes the '628 Patent" and its position "remains unchanged."
 - 18. GCE has not infringed, and does not infringe, any claim of the '628 Patent.
- 19. Nearly two years later and armed with yet another patent, Defendant resumed communications with GCE in 2022. On July 28, 2022, Defendant sent another letter to GCE representing that 3B Medical Manufacturing, LLC is the exclusive licensee of the '628 Patent and asserting that GCE infringes the '628 Patent by manufacturing and selling the Zen-O lite system. Additionally, Defendant represented that 3B Medical Manufacturing, LLC is the exclusive licensee of the '614 Patent and asserted that GCE infringes the '614 Patent by manufacturing and selling the Zen-O lite system. The letter states that "GCE is infringing the [']628 Patent and/or the [']614 Patent by making, using, offering for sale, selling, and/or

importing, without license or authority, the Zen-O [l]ite [system] that directly and/or indirectly infringes the [']628 (at least claims 1 and/or 11) and/or [']614 Patents (at least claim 1)."

- 20. In the July 28, 2022 letter, Defendant demanded that "GCE immediately cease all infringing activities related to the Zen-O [l]ite[.]" Defendant threatened that it will "take additional steps as [Defendant] deem[s] necessary," if GCE does not provide a response.
 - 21. GCE has not infringed, and does not infringe, any claim of the '614 Patent.
- 22. GCE has not infringed, and does not infringe, any claim of 3B's earlier patent, the '628 Patent.
- 23. As a result of Defendant's allegations and threats, a substantial controversy exists between the parties, who have adverse legal interests, and this controversy is of sufficient immediacy, reality, and ripeness to warrant the issuance of a declaratory judgment. Without a judicial declaration that Defendant's infringement allegations are meritless, GCE will suffer prejudice and harm, and be forced to operate under a cloud of uncertainty as to whether its acts are lawful.

COUNT I (Declaration of Non-Infringement of the '628 Patent)

- 24. GCE realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 25. Defendant has accused GCE's Zen-O lite system of infringing at least claims 1 and 11 of the '628 Patent and has threatened legal action against GCE on this basis.
 - 26. GCE's Zen-O lite system does not infringe any claim of the '628 Patent.
- 27. By way of example, claims 1 and 11 each require a separation cartridge comprising a bed of adsorbent material, an inlet port, and an outlet port, all oriented in a certain way. More specifically:

Claim 1 of the '628 Patent requires:

a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material; . . .

wherein the bed of adsorbent material is disposed along an axis, one of the inlet and the outlet is disposed along the axis, and the other of the inlet and the outlet is spaced-apart from the axis, and wherein the first direction and the second direction are substantially parallel to the axis.

Claim 11 of the '628 Patent requires:

a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction and a bed of adsorbent material configured to preferentially adsorb nitrogen; and . . .

wherein the bed of adsorbent material is disposed along an axis, wherein one of the inlet and the outlet is disposed along the axis, wherein the other of the inlet and the outlet is spaced-apart from the axis, and wherein the first direction and the second direction are substantially parallel to the axis.

- 28. GCE's accused Zen-O lite system does not satisfy the required limitations of the asserted claims of the '628 Patent and therefore there can be no infringement.
- 29. GCE's non-infringement positions set forth herein are based on its current understanding of the Defendant's claims and claim interpretations. GCE reserves the right to revise or supplement its non-infringement positions as it gains further understanding of Defendant's assertions through discovery.
- 30. An actual, present, and justiciable controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between GCE and Defendant concerning

GCE's right to manufacture and sell the Zen-O lite system and any similar products and GCE's right to engage in related activities.

- 31. GCE seeks declaratory judgment from this Court that GCE's production and sale of the Zen-O lite system and any similar products, and GCE's related activities, do not infringe the '628 Patent.
- 32. GCE seeks declaratory judgment that Defendant has suffered no, and will not suffer any, cognizable damages or loss of goodwill because of GCE's production and sale of the Zen-O lite system and any similar products or because of GCE's related activities.
- 33. GCE seeks a declaratory judgment that Defendant is not entitled to injunctive relief or damages under 35 U.S.C. §§ 283-84.
- 34. Such declarations are necessary and appropriate at this time so that GCE may confirm its rights with respect to the production and sale of the Zen-O lite system and any similar products and with respect to GCE's related activities.

COUNT II(Declaration of Non-Infringement of the '614 Patent)

- 35. GCE realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 36. Defendant has accused GCE's Zen-O lite system of infringing claim 1 of the '614 Patent and has threatened legal action against GCE on this basis.
 - 37. GCE's Zen-O lite system does not infringe any claim of the '614 Patent.
- 38. By way of example, claim 1 requires a separation cartridge comprising a bed of adsorbent material, an inlet port, and an outlet port, all oriented in a certain way. More specifically:

Claim 1 of the '614 Patent requires:

- a separation cartridge selectively removable from a receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen;
- 39. GCE's accused Zen-O lite system does not practice the required limitations of the asserted claims of the '614 Patent and therefore there can be no infringement.
- 40. GCE's non-infringement positions set forth herein are based on its current understanding of the Defendant's claims and claim interpretations. GCE reserves the right to revise or supplement its non-infringement positions as it gains further understanding of Defendant's assertions through discovery.
- 41. An actual, present, and justiciable controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between GCE and Defendant concerning GCE's right to manufacture and sell the Zen-O lite system and any similar products and GCE's right to engage in related activities.
- 42. GCE seeks declaratory judgment from this Court that its production and sale of the Zen-O lite system and any similar products, and GCE's related activities, do not infringe the '614 Patent.
- 43. GCE seeks declaratory judgment that Defendant has suffered no, and will not suffer any, cognizable damages or loss of goodwill because of GCE's production and sale of the Zen-O lite system and any similar products or because of GCE's related activities.
- 44. GCE seeks a declaratory judgment that Defendant is not entitled to injunctive relief or damages under 35 U.S.C. §§ 283-84.

45. Such declarations are necessary and appropriate at this time so that GCE may confirm its rights with respect to the production and sale of the Zen-O lite system and any similar products and with respect to GCE's related activities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff GCE prays for judgment in its favor and against Defendant and specifically for the following relief:

- 1. Entry of judgment according to the declaratory relief sought, in favor of GCE and against Defendant, on each of GCE's claims;
- 2. Declaratory judgment that the manufacture, use, offer to sell, sale, and importation of GCE's Zen-O lite system and any similar products does not infringe any claim of the '628 Patent and that GCE does not infringe the '628 Patent in any way;
- 3. Declaratory judgment that the manufacture, use, offer to sell, sale, and importation of GCE's Zen-O lite system and any similar products does not infringe any claim of the '614 Patent and that GCE does not infringe the '614 Patent in any way;
- 4. Declaratory judgment that Defendant is not entitled to any injunctive relief with respect to the manufacture, use, offer to sell, sale, and importation of GCE's Zen-O lite system and any similar products or with respect to any of GCE's activities;
- 5. Declaratory judgment that Defendant has not suffered any, and will not suffer any, cognizable damages because of GCE's production and sale of the Zen-O lite system and any similar products, and GCE's related activities, and thus is not entitled to any relief under federal patent law;

- 6. An award of reasonable attorneys' fees, to the extent authorized by law;
- 7. An award of GCE's costs and expenses in this action; and
- 8. All such other and further costs and relief as to which GCE may be entitled as a matter of law or equity, or which the Court determines to be just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, GCE demands a trial by jury on all issues raised by the Complaint that may be so tried.

Dated: October 5, 2022 Respectfully submitted,

By: /s/ Robert M. Masters

SHEPPARD, MULLIN, RICHTER &

HAMPTON LLP

Robert M. Masters (Bar No. 14770)

Timothy P. Cremen (pro hac vice forthcoming)

2099 Pennsylvania Avenue, N.W.

Suite 100

Washington, DC 20006-6801

Telephone: 202.747.1900

Facsimile: 202.747.1901

RMasters@sheppardmullin.com TCremen@sheppardmullin.com

Eric K. Gill (*pro hac vice* forthcoming)

12275 El Camino Real, Suite 100

San Diego, CA 92130-4092

Telephone: (858) 720-8900

Facsimile: (858) 509-3691

EGill@sheppardmullin.com

Attorneys for Plaintiff